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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,722	03/25/2004	Jennifer Beck	BKP-012	5639
22832	7590	03/03/2008	EXAMINER	
Kirkpatrick & Lockhart Preston Gates Ellis LLP (FORMERLY KIRKPATRICK & LOCKHART NICHOLSON GRAHAM) STATE STREET FINANCIAL CENTER One Lincoln Street BOSTON, MA 02111-2950			DOUGLAS, STEVEN O	
		ART UNIT	PAPER NUMBER	
		3771		
		MAIL DATE		DELIVERY MODE
		03/03/2008		PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/808,722	<b>Applicant(s)</b> BECK ET AL.
	<b>Examiner</b> /Steven O. Douglas/	<b>Art Unit</b> 3771

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 11 February 2008.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-30 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 9-14 and 25-30 is/are allowed.  
 6) Claim(s) 1-8 and 15-23 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/1449B)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Sinderby et al. (WO 99/62580).

The Sinderby et al. reference discloses a apparatus for controlling positive pressure assist to a patient during expiration comprising a detector of a level of electrical activity of a patients respiration related muscle (see Figure 2) and a controller that includes a neuro-ventilatory efficiency computation device 601 to control the operation of a level of pressure assist by unit 604. Furthermore, the Sinderby et al. reference discloses a control arrangement 700 in Figure 11 to detect preset levels of EMG intensity to control the automatic operation of PEEP ventilation. Also, attention is directed to page 7, lines 22-26 where it is further stated that the Sinderby et al. device is applicable with any respiratory muscle signal (i.e. *that includes at least inspiration and expiration*). Essentially, Sinderby et al. includes all the components necessary and is capable of measuring a level of electrical activity of a patient's diaphragm during expiration and controlling a level of pressure assist during such expiration event.

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Sinderby et al.

The Sinderby et al. reference discloses an apparatus including all of the required components to practice the method as claimed (as discussed above). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the Sinderby et al. device to practice the method as claimed, since the Sinderby et al. device is certainly capable of measuring a level of electrical activity of a patient's diaphragm during expiration and controlling a level of pressure assist during such expiration event and practicing the method as claimed..

*Response to Arguments*

Applicant's arguments filed 2/11/08 have been fully considered but they are not persuasive. Again in regard to Applicant's argument that the Sinderby et al. reference fails to explicitly disclose the sensing of electrical activity during expiration and controlling a level of pressure assist to the patient, Examiner again agrees at least in part. Although the Sinderby et al. reference may not disclose sensing electrical activity during expiration, attention is directed above where Examiner has taken the position that the Sinderby et al. is most certainly capable of sensing such activity and controlling the level of pressure as claimed, especially since all of the required components to achieve such function are disclosed by Sinderby et al.

***Conclusion***

Claims 24 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 9-14 and 25-30 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to /Steven O. Douglas/ whose telephone number is (571) 272-4885. The examiner can normally be reached on Mon-Thurs 6:30-5:00.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Steven O. Douglas/  
Primary Examiner  
Art Unit 3771

SD  
2/21/08

